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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/258,553	02/26/99	WEAVER	F	[illegible]

HM12/1011

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EXAMINER
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ART UNIT	PAPER NUMBER
[illegible]	7

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/258,553	Applicant(s) Weaver, E.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Jul 17, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-17* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2 and 3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election without traverse of Group II, claims 10-17, in Paper No.6, is acknowledged.

Claims 10-17 are pending and being acted upon.

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification does not reasonably provide enablement for the method above comprising:

A) a method of preventing infection and disease from verotoxin-producing bacteria in animals comprising: internally administering a composition to an animal which comprises polyclonal, monospecific antibodies isolated from natural animal serum (claim 10),

B) a method of preventing infection and disease from verotoxin-producing bacteria ... wherein the composition is administered in a dose of from about 1 g to about 30 g of plasma protein per day" (claim 13).

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. The claims are not commensurate with the enablement provided by the disclosure with regard to the use of the compositions encompassed by the claims.

Regarding A, the specification provides insufficient working examples that the claimed composition prevents disease. The term "preventing" denotes absolute 100% inhibition of a forthcoming disease (See enclosed Webster's definition). The specification fails to provide any guidance as to how the disclosed immunoglobulin (Ig) composition would 100% inhibit any type of verotoxin-induced disease. The current state of the art of medical therapies has not demonstrated a therapy capable of preventing a disease. The single working example that provides treatment data discloses only that the Ig composition-fed animals

gain 9% more weight over an undisclosed period of time than do control animals. Disease prevention is not addressed by the example (Example 1). Given the teaching of Lissner et al. (1996, IDS) that protection against verotoxin-producing bacteria has been demonstrated only after intravenous administration of immunoglobulins, and that said administration was only efficacious if done in an early disease stage (see particularly page 381, column 2, lines 1-10), the prevention of verotoxin-induced disease through the passive administration of antibodies in feed would be highly unpredictable. Additionally note that as recited, claim 10 claims that the feeding of *any* animal serum composition to *any* animal would prevent *any* verotoxin-induced disease, e.g., the feeding of a human Ig composition to humans would prevent verotoxin-induced disease.

Regarding B, the specification provides no working examples demonstrating that the composition if administered in a dose of from about 1 g to about 30 g of plasma protein per day has any effect whatsoever. In the single disclosed example, the Ig composition is simply added to the animals' water supply, no data is disclosed establishing how much of the composition was actually ingested by each animal. As in A, supra, given that the prevention of verotoxin-induced disease through the administration of an oral immunoglobulin composition has not been demonstrated in *any* concentration, the claim to prevention by the administration of said composition in a specific dosage has also not been demonstrated and thus would also be unpredictable.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the recitation of the undefined term "natural serum" in claim 10 renders the claim ambiguous and indefinite. The recitation of said term implies the existence of unnatural serum and that said unnatural serum somehow differs from natural serum.

6. No claim is allowed.

7. The claimed method of prevention of verotoxin-induced disease appears to be free of the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

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October 7, 2000

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